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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,852	11/07/2001	Alan M. Kinnersley	7224-65	8960

7590

04/20/2005

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,852	Applicant(s) KINNERSLEY ET AL.	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-32,34,36-39 and 41-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-32,34,36-39 and 41-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed on January 28, 2005 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 29, 2004 has been entered.

Claims 1-30, 33, 35 and 40 are cancelled.

Claims 31-32 and 38 are currently amended.

Claims 41-54 are newly added.

Claims 30-32, 34, 36-39 and 41-54 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 31, 34, 36-39, 41, 43-48, 50-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention, for the reasons of record set forth in the office action mailed July 29, 2004.

Applicants' arguments filed November 29, 2004, have been fully considered but they are not fully persuasive.

Applicants maintain that that this rejection is overcome by the amendment of the claims to recite an amino acid sequence identity level of at least 70%. Applicants point out that the Declaration Under 37 C.F.R. 1.132 of record in the present case (April 23, 2004) sets forth identity comparisons of each amino acid sequence set forth in the Sequence Listing, and that these comparisons reveal that each pair has from 72.8% to 91.2% identity to one another. Applicants submit that the disclosure of nine amino acid sequences within this range of identity values when compared to one another provides adequate descriptive support of the genus recited in the claims. (reply page 11)

Applicants arguments are inapposite to the instant rejection because the rejected claims are not limited to the use of polynucleotides encoding plant GAD enzymes comprising an amino acid sequence having at least 70% identity to the sequence set forth in SEQ ID NO:2. Rejected claims 31, 34, 36-37, 41, 43-45 and 48-52 are drawn to the use of polynucleotides encoding plant GAD enzymes of any unspecified structure, and rejected claims 38-39, 46-47 and 53-54 are drawn to the use of polynucleotides encoding GAD enzymes of any unspecified structure obtained from any unspecified source. The Examiner maintains that the disclosure of nine polynucleotides encoding GAD enzymes obtained from four different species of dicotyledonous plants and comprising amino acid sequence having from 72.8% to 91.2% identity to one another

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does not adequately describe polynucleotides encoding all plant GAD enzymes, or polynucleotides encoding all GAD enzymes.

Claims 30-32, 34, 36-39 and 41-54 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making a transformed plant by transforming a plant with a vector comprising a constitutive promoter operably linked to a polynucleotide that encodes a plant GAD enzyme that does not include a functional autoinhibitory calmodulin-binding domain and selecting a transformed plant that (i) has high GABA (0.29-0.39 mg/GDW), is stunted, and produces little or no seed as compared to compared to wild type control plants, (ii) has moderately higher GABA (0.15 mg/GDW), is taller, and produces viable seed as compared to compared to wild type control plants, or (iii) has normal or below normal GABA levels (.05-.10 mg/GDW) and appears normal, does not reasonably provide enablement for methods that involve expressing plant GAD enzymes under the control of non-constitutive promoters, or methods that involve expressing GAD enzymes other than plant GAD enzymes that do not include a functional autoinhibitory calmodulin-binding domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed July 29, 2004.

Applicants' arguments filed November 29, 2004, have been fully considered but they are not fully persuasive.

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Applicants maintain that the rejection is moot in view of the cancellation of all the claims previously rejected under this section of the statute (reply page 11).

The Examiner maintains that while the rejection may be moot with respect to the cancelled claims, the rejection is maintained because the currently amended and newly added claims incorporate the limitations of the claims previously rejected under this section of the statute.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 38, 41, 46, 48 and 53, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31, 38, 41, 46, 48 and 53 are indefinite in the recitation of "significant". It is unclear how much loss of reproductive function, loss of yield or stunting would be significant. With respect to claims 31 and 38, it is also unclear what the loss of reproductive function is significant in comparison to.

Claims 31 and 38, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 31 and 38 are indefinite in the recitation of "reproductive function". It is unclear what aspect of reproductive function is not lost, since various distinct parts of the plant participate in reproduction (e.g. stamens, stigma,

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style, ovary, etc.), and since the expression of a single polypeptide would not be expected to affect all aspects of reproductive function.

Claims 41 and 46, and claims dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 41 and 46 are indefinite in the recitation of "yield". It is unclear what aspect of yield is not significantly lost, since yield may be determined in different ways (e.g. yield of fruit, yield of seed, vegetative yield, dry weight, fresh weight, etc.), and since the expression of a single polypeptide would not be expected to affect all types of yield determinations.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

 4/18/05